EPA/OPP MICROBIOLOGY LABORATORY ESC, Ft. Meade, MD

Standard Operating Procedure for VITEK: Establishment of Culture Identification Numbers

SOP Number: QC-16-02

Date Revised: 08-22-02

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1.0 <u>SCOPE AND APPLICATION</u>:

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1.1 This protocol describes the tracking of cultures during the confirmation process using the Vitek 32 System for the Automated Identification of Microorganisms.

- 2.0 DEFINITIONS: None
- 3.0 HEALTH AND SAFETY:
 - 3.1 Laboratory personnel should follow biosafety procedures appropriate for the organism being confirmed as outlined in SOP MB-01, Biosafety in the Laboratory.
- 4.0 <u>CAUTIONS</u>: None
- 5.0 INTERFERENCES:
 - 5.1 Be especially careful when you mark Vitek cards with Identification Numbers. The system reads missing digits as 0 (zero) and questionable digits as question marks. The only areas to be marked are the figure eights for the Vitek ID and the external test result marks for oxidase, catalase, coagulase, etc. Do not mark near any of the wells as this could cause erroneous interpretations and results (see Sect. 10.2.2).

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS:

7.1 Vitek 32 System for the automated identification of microorganisms.

8.0 INSTRUMENT OR METHOD CALIBRATION:

- 8.1 See SOP QC-17, VITEK: Quality Control Procedures.
- 9.0 <u>SAMPLE HANDLING AND STORAGE</u>: Not applicable

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10.0 PROCEDURE AND ANALYSIS:

10.1 Assigning Identification Numbers

10.1.1 A unique seven digit Vitek ID number is assigned to each culture which is evaluated by the Vitek system. Numbers are assigned sequentially and are pre-established on the Vitek Microbe Identification Log (see 16.1). For each unknown, fill in the information fields on the Vitek Microbe Identification Log prior to seeding the card. The identification number will be entered directly onto the Vitek card and will appear on the top left corner of the Vitek printout (see 16.2).

10.2 Labeling Vitek Cards

10.2.1 Find the series of square figure eights stamped at the top left of the card. This is where you mark the Vitek ID. The system scans this part of the card for the Vitek ID. It must be machine-readable (written in dark squared-off numbers). When you mark the Vitek ID, keep the numbers square and plain like those in the legal character set below.

1234567890

10.2.2 Confirm the machine has read the cards correctly after they enter the assay chamber. Erroneous or questionable digits may be corrected in one of two ways. First, remove the card from the Reader/Incubator when the tray rotates to the door and mark the card again. Always re-insert cards back into their original slots. Second, errors may also be corrected on the computer using the qualifier button. The qualifier button on the status window indicates the number of cards in the selected directory that have a question mark in the Vitek ID number. Incorrect digits and question marks may be edited by entering corrections and saving them (see ref. 15.1).

11.0 DATA ANALYSIS/CALCULATIONS: None

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12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Data will be recorded promptly, legibly, and in indelible ink. Information on confirmation will be recorded on the Vitek Microbe Identification Log Book (see 16.1). Completed forms are archived in notebooks kept in locked file cabinets in file room D217. Only authorized personnel have access to the locked files. Archived data is subject to OPP's official retention schedule contained on SOP ADM-03, Records and Archives.

13.0 **QUALITY CONTROL**:

13.1 The OPP Microbiology Laboratory conforms to 40CFR Part 160, Good Laboratory Practices. Appropriate quality control measures are integrated into each SOP.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 If an identification number is not assigned to a culture or cannot be interpreted by Vitek, then the sample must be reanalyzed; a new card must be reloaded and the appropriate identification number assigned.

15.0 REFERENCES:

15.1 bioMerieux Vitek, Inc. 1996. Industrial Vitek Procedures Manual with Supplement 512631-1, Rev 0996.

16.0 FORMS AND DATA SHEETS:

- 16.1 Vitek Microbe Identification Log
- 16.2 Sample Vitek Printout

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VITEK Microbe Identification Log OPP/Microbiology Laboratory

VITEK Microbe Identification Log							
Date/Init.	Vitek No.#	Card*	Test Date	Product Reg. No.	Test Organism	Sample No.	
	000001-0						
Comments:							
	000002-0						
Comments:							
	000003-0						
Comments:							
	000004-0						
Comments:							
	000005-0						
Comments:							
	000006-0						
Comments:							
	000007-0						
Comments:							

- * Indicate the Vitek card type as GP (Gram Positive card), GNI+ (Gram Negative card), or B (Bacillus card)
- + For example, indicate the Use Dilution Test carrier tube the culture originated from (1-60, primary or secondary)
- # The Vitek number appears on the Vitek report printout.

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Sample Vitek Printout OPP/Microbiology Laboratory

bioMarioux Vitak Manual Vitak Lah Raport

	Vitek ID: Type: Status: Elapsed Time: Organism: Biommber:	600101-0 (A Becillus Car Final 10 hours Becillus lic 27250767350	henifornis	phile			
	1250 - 621 - 262 - 502 - 6110 -	500 + 101 - 1107 - 1148 + 1111 +	TIR - TIL - PIE - MY + ARS -	TAG + 1036 + 1037 + 1038 + 1046 +	ELU + ELF - TEL + ELL +	IND + SAL + PLA + NUM + ESC +	
:	95 % Bacillus 1 % Bacillus						